RESEARCH ARTICLE

Editorial Process: Submission:12/30/2023 Acceptance:05/10/2024

Comparison of Sexual Function after Thermal Ablation Versus Loop Electrosurgical Excision Procedure (LEEP) for Cervical Intraepithelial Neoplasia (CIN 2 and 3): A Randomized Controlled Trial

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Abstract

Background: The prevention of cervical cancer can be achieved by treating high-grade cervical precancerous lesions. Treatment options for cervical precancer include excisional procedures, and ablation treatments. Despite the long pre-invasive course of the disease, literature addressing sexual function post-treatment for cervical pre-invasive lesions is scarce. This study aims to bridge this gap and assess the sexual function and the acceptability, efficacy, safety, and complications of loop electrosurgical excision procedure (LEEP) versus thermal ablation. **Methods:** The prospective open-label randomized controlled trial recruited women aged 22-55 with histologically confirmed Cervical Intraepithelial Neoplasia (CIN) 2 and 3 lesions. Participants were randomly allocated to either thermal ablation or LEEP. All cases were followed up with a Pap smear at three- and six-months post treatment. Sexual health assessments were conducted using a questionnaire at baseline and 3 months post-procedure. Secondary outcome measures included comparison of acceptability, pain, and side effects between the two treatment measures. **Results:** Out of 1356 screened cases, 60 were included in the study and randomized in two groups. The groups had similar baseline characteristics. Duration of LEEP was longer than thermal ablation (25.33 vs. 20.67 minutes), with higher pain reported 10 minutes post-procedure in the LEEP group. Three months post-procedure, both groups showed comparable acceptability and symptom relief. Sexual function parameters significantly improved in the thermal ablation group compared to LEEP, including satisfaction, desire, lubrication, flexibility, and ability to reach climax. **Conclusion:** LEEP and thermal ablation are effective treatments for CIN with similar efficacy at 6 months. Thermal ablation demonstrated advantages in procedure time and post-procedural pain but exhibited varying effects on sexual function, improving satisfaction and desire. In contrast, LEEP showed a decrease in satisfaction and potential alterations in lubrication and flexibility. Larger-sample, longer-term studies are recommended for further insights.

Keywords: CIN- HSIL- LEEP- Pap smear- sexual function- sexual health- thermal ablation

Asian Pac J Cancer Prev, **25 (5)**, 1699-1705

Introduction

About 90% of cervical cancer deaths occur in low- and middle-income countries (LMICs), mainly due to insufficient preventive and screening opportunities along with limited treatment options [1]. Screening using Papanicolaou (Pap) smear, colposcopy, and excisional or ablative intervention has led to early detection and treatment of pre-invasive lesions of the cervix [2]. Cervical cancer predominantly affects women in their reproductive years when most women are sexually active. Treatment of cervical cancer includes surgery or chemoradiation [2]. Several studies have been published in the literature that explore the sexual function in women after treatment of cervical cancer with radical hysterectomy or chemoradiotherapy [3]. Although the disease has a long pre-invasive course, there is paucity of literature on the sexual function post treatment of cervical pre-invasive lesion. WHO recommends that loop electrosurgical excision procedure (LEEP) or cryotherapy or thermal ablation may be used to treat histologically confirmed CIN2+ disease depending on availability of expertise, training, equipment, infrastructure and resources [4].

LEEP involves excision of a small section of the cervix while thermal ablation involves thermocoagulation of the transformation zone initiating a healing process

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within the cervical tissue without affecting the vagina. It remains uncertain whether this surgical procedure could induce a persistent inflammatory process, potentially having a detrimental effect on female sexual function, or conversely, serve as a secondary treatment for cervicitis, thereby improving pre-existing dyspareunia [5]. Very few studies have assessed sexual function post LEEP while there have been no randomized studies in the literature comparing the sexual function after LEEP and thermal ablation. The aim of the present study was to address these lacunae in literature and to assess the acceptability, efficacy, safety and complications between the two procedures.

Materials and Methods

This was a prospective open label randomized controlled study conducted at tertiary care centre from July 2020 to January 2022 after obtaining ethical clearance from institute ethics committee (AIIMS/IEC/20/653). The trial was registered with the clinical trial registry of India (CTRI/2021/03/032424). Informed written consent was taken from each study participant. Inclusion criteria were women aged 22-55 years, screened positive with high-risk HPV or visual inspection with acetic acid (VIA), histologically confirmed CIN 2 and 3 lesions, abnormal cytology including Low-grade Squamous Intra-Epithelial Lesion (LSIL) and High-grade Squamous Intra-Epithelial Lesion (HSIL) and type 1 transformation zone (TZ) and type 2 TZ where probe tip could achieve complete ablation of the squamocolumnar junction (Tip could reach upper limit of the TZ). Exclusion criteria included obvious cervical growth on per-speculum examination, high suspicion of cervical cancer, preinvasive lesion occupying more than two quadrants of cervix or with vaginal and/or endocervical extension, type 3 TZ and type 2 TZ where SCJ could not be completely covered with probe tip. Pregnant women, women with history of pelvic irradiation and women with severe debilitating disease were excluded. Randomization was done using a computer-generated randomization table in order to allocate the groups in the ratio of 1:1.

Cases attending the outpatient department were screened using Pap smear, visual inspection with acetic acid (VIA) and visual inspection with lugol's iodine (VILI). Cases with abnormal report were managed with colposcopy and guided biopsy and cases with histopathology report suggestive of CIN 2 and 3 were recruited.

Post treatment women were advised to attend for clinical follow-up at 1, 3 and 6 months after treatment. Assessment of sexual health and sexual function was done at baseline prior to treatment and at the follow up visit scheduled at 3 months after the procedure using the questionnaire. The questionnaire was composed of: (i) general questions about frequency of sexual intercourse, the presence of dysmenorrhea, dyspareunia, and postcoital bleeding; and (ii) specific patient-rated questions on overall satisfaction with sexual intercourse, sexual desire, vaginal lubrication, vaginal elasticity, orgasmic satisfaction, patient-perceived partner's satisfaction, and associated anxiety. The parameters were scored on a 6-point Likert scale with responses ranging from 0 being the lowest to 5 being the highest. The questionnaire was created through literature review and validated by pretesting on 10% of the population. The internal reliability of the questionnaire was evaluated using Cronbach's alpha coefficient, showing good internal consistency with values of 0.78 before the procedure and 0.74 after the procedure.

Data analysis was done using Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 21.0. The quantitative variables not normally distributed were analyzed using Mann-Whitney Test and Independent t test was used for comparison of normally distributed data between two groups. Wilcoxon signed rank test was used for comparison of sexual function between before and after treatment. Qualitative variables were analysed using Chi-Square/ Fisher's exact test. P value of less than 0.05 was considered statistically significant.

Results

A total of 1,356 cases were screened. Of these 7.96% (n=108) were found to have abnormal Pap smear or VIA/ VILI positive and were further managed by colposcopy and guided biopsy. Sixty cases with histologically confirmed CIN 2 and 3 lesion were included in the study and were randomized into either of the 2 treatment modalities: thermal coagulation and LEEP (Figure 1).

The mean age of the study population was 44.25 ± 7.29 years. Baseline characteristics were similar between the two groups (Table 1). The mean age at the time of first sexual intercourse was 18.9 ± 1.46 years while the mean age at the time of first child birth was 20.38 ± 1.57 years. The distribution of cases between the two treatment modalities was similar based on the screening tests used as shown in Table 2. Following colposcopy and guided biopsy there were 86.67% (n=26) cases of CIN 2 in thermal ablation group and 73.33% (n=22) cases in the LEEP group while there were 13.33% and 26.67% cases on CIN 3 in the two groups respectively.

The duration for LEEP was significantly higher compared to thermal ablation (25.33 ± 5.07 versus 20.67 ± 2.54; P= <0.001) while cases reported significantly higher pain 10 minutes post procedure in the LEEP group (Table 3). Acceptability and symptom relief 3 months post procedure was comparable between the two groups. All cases reported pain post procedure and the side effects were comparable between the groups. Table 4 shows the comparison of Pap smear reports between the two groups at 3- and 6-months post treatment and they were comparable between both the groups. Post LEEP there were 18 cases with histopathological report of CIN 2 and 6 cases with CIN 3. The distribution of histopathological diagnosis of cases prior to and post LEEP are shown in Figure 2.

Three cases from the thermal ablation group and 6 cases from the LEEP declined to complete the sexual function questionnaire. Cases treated with thermal ablation reported a significant improvement in parameters like level of satisfaction, level of sexual desire or interest and vaginal

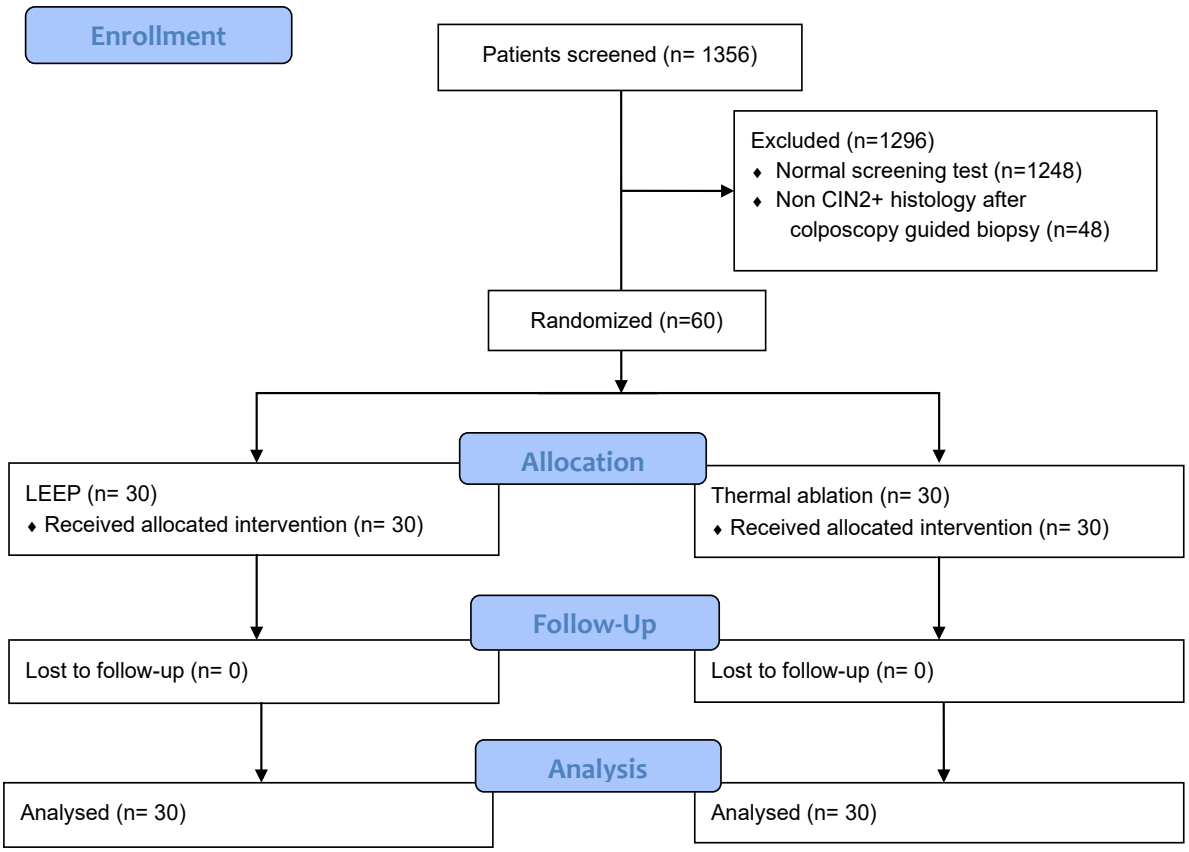

Figure 1. CONSORT Flow Diagram

Table 1. Baseline Characteristics

Socio-demographic characteristics	Thermal ablation (N=30)	LEEP (N=30)	P value
Age (years)$	44 ± 7.4	44.5 ± 7.29	0.793‡
Education n(%)			0.312*
Illiterate	3 (10%)	3 (10%)	
Primary school	6 (20%)	7 (23.33%)	
High school	15 (50%)	15 (50%)	
Intermediate	6 (20%)	2 (6.67%)	
Graduate	0 (0%)	3 (10%)	
Socio-economic status n(%)			0.637*
Upper middle	4 (13.33%)	4 (13.33%)	
Lower middle	19 (63.33%)	22 (73.33%)	
Upper lower	3 (10%)	3 (10%)	
Lower	4 (13.33%)	1 (3.33%)	
Parity [median (IQR)]	2 (2-3)	2 (2-4)	0.272§
Age at the time of first intercourse (years)$	18.97 ± 1.59	18.83 ± 1.34	0.726‡
Age at the time of first child birth (years)$	20.5 ± 1.76	20.27 ± 1.39	0.57‡
Contraception n(%)			0.922*
Nil	11 (36.67%)	7 (23.33%)	
Not sexually active	2 (6.67%)	3 (10%)	
Barrier contraceptives	2 (6.67%)	5 (16.66%)	
Copper T	1 (3.33%)	1 (3.33%)	
Ligated	6 (20%)	7 (23.33%)	
Oral Contraceptive Pills	6 (20%)	7 (23.33%)	

$, mean ± SD; ‡, Independent t test; §, Mann Whitney test; *, Fisher's exact test; †, Chi square test

Table 2. Comparison of Cases Based on the Screening Test

Screening test	Thermal ablation (N=30) n (%)	LEEP (N=30) n (%)	P value
VIA			0.299*
Negative	7 (23.33%)	3 (10%)	
Positive	23 (76.67%)	27 (90%)	
VILI			0.347†
Negative	8 (26.67%)	5 (16.67%)	
Positive	22 (73.33%)	25 (83.33%)	
Pap Smear			0.614†
ASC-H $	16 (53.33%)	15 (50%)	
HSIL	5 (16.67%)	8 (26.67%)	
LSIL	9 (30%)	7 (23.33%)	
Colposcopy guided biopsy			0.333*
CIN 2	26 (86.67%)	22 (73.33%)	
CIN 3	4 (13.33%)	8 (26.67%)	

*, Fisher's exact test; †, Chi square test; $, Atypical squamous cells - cannot exclude high grade squamous intraepithelial lesion

self-lubrication, on the contrary post LEEP poor scores were noted in all the parameters except level of sexual desire or interest and anxiety. There was no significant difference of the parameters of sexual function between the two groups before the procedure while the cases reported significantly better parameters of sexual function post thermal ablation compared to LEEP except for pain or discomfort during penetration Table 5,6.

Discussion

LEEP and thermal ablation are widely accepted for the management of CIN 2 and 3 lesions. Consistent with the systematic review and meta-analysis by Piret EM et al. (2022), thermal ablation had a high acceptability comparable with that of LEEP [6]. Procedure time for thermal ablation and pain at 10 mins post procedure were lower in thermal ablation compared to LEEP, however at six months there was no significant difference in the post-procedure cytology.

The impact of LEEP and thermal ablation on women's sexuality remains unclear, with limited understanding from published studies. The etiology of sexual problems

Table 3. Procedure Parameters, Acceptability and Side Effects

Parameters	Thermal ablation (N=30)	LEEP (N=30)	P value
Procedure duration (minutes)$	20.67 ± 2.54	25.33 ± 5.07	<0.0001§
Pain (10 minutes post procedure)$	3.87 ± 0.51	4.27 ± 0.45	0.003§
Acceptability (Likert scale: 1-7)$	5.73 ± 0.58	5.6 ± 0.5	0.408§
Symptom relief n (%)	20 (66.67%)	18 (60%)	0.592†
Side effects n (%)			
Pain	12 (40%)	15 (50%)	0.436†
Minimal blood loss during procedure	0 (0%)	24 (100%)	<0.001*
Cervical stenosis	12 (40%)	16 (53.33%)	0.301†
Need for other surgeries (Hysterectomy)	5 (16.67%)	6 (20%)	0.739†

$, mean ± SD; §, Mann Whitney test; †, Chi square test; *, Fisher's exact test

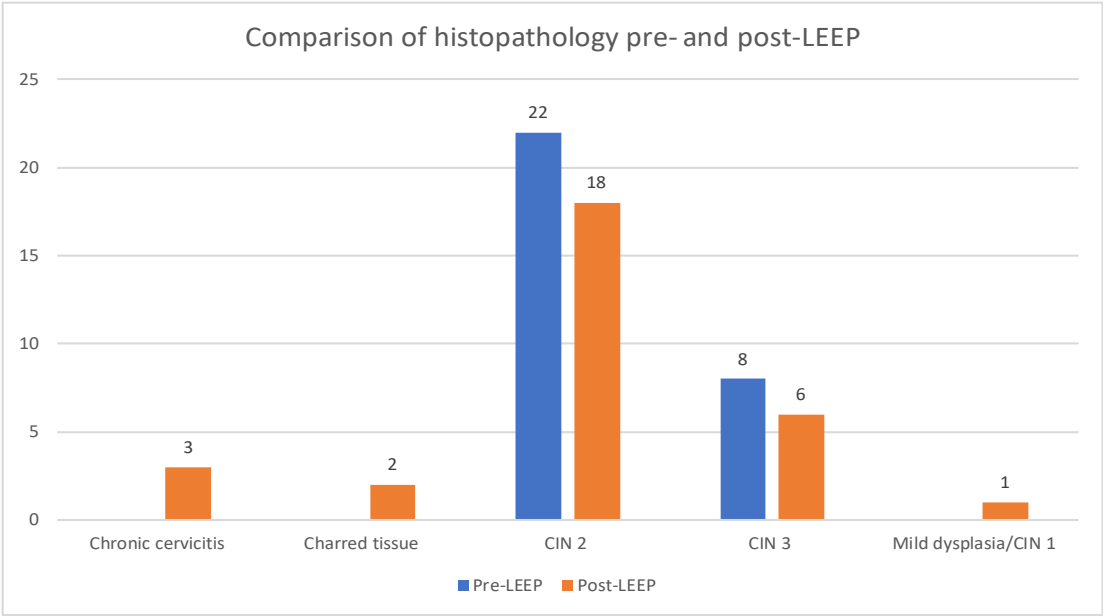

Figure 2. Histopathology Reports Pre- and Post-LEEP

Table 4. Follow-up Pap Smear at 3- and 6-months Post Procedure

Pap smear	Thermal ablation (N=30) n (%)	LEEP (N=30) n (%)	P value
3 months			0.053*
ASC H	1 (3.33%)	2 (6.67%)	
ASC-US	0 (0%)	2 (6.67%)	
HSIL	5 (16.67%)	0 (0%)	
LSIL	2 (6.67%)	1 (3.33%)	
NILM	22 (73.33%)	25 (83.33%)	
6 months			0.637*
ASC-H	2 (6.67%)	3 (10%)	
ASC-US [$]	0 (0%)	2 (6.67%)	
HSIL	3 (10%)	1 (3.33%)	
LSIL	2 (6.67%)	1 (3.33%)	
NILM	23 (76.67%)	23 (76.67%)	

*, Fisher's exact test; [$], Atypical squamous cells - cannot exclude high grade squamous intraepithelial lesion

Table 5. Comparison of Sexual Function pre- and post- Procedure

Sexual function	Pre-thermal coagulation (n=27)	Post-thermal coagulation (n=27)	P value[¶]	Pre-LEEP (n=24)	Post-LEEP (n=24)	P value[¶]
Level of satisfaction	3.3±0.47	3.07±0.27	0.014	3.08±0.41	2.25±0.61	0.0002
Level of sexual desire or interest	2.63±0.49	3±0.39	0.002	2.42±0.5	2.17±0.7	0.227
Vaginal self-lubrication	2.56±0.51	3±0.39	0.001	2.42±0.65	2±1.02	0.021
Flexibility of vagina	2.7±0.47	2.93±0.62	0.109	2.58±0.5	2.17±0.7	0.035
Ability to reach climax	2.7±0.47	2.63±0.74	0.593	2.58±0.5	2±0.72	0.004
Level of anxiety related to sexual life	2.33±0.48	2.08±0.78	0.269	2.44±0.51	2.56±0.64	0.257
Overall level of patient perceived partner satisfaction	2.7±0.47	2.93±0.47	0.058	2.83±0.38	2.17±0.38	<0.0001

Data presented as mean±SD; [¶], Wilcoxon Signed Ranks Test

in such patients is multifactorial, involving psychological, physiologic, and sociological factors. Hence, addressing sexual health concerns in these individuals is complex. Sexual disinterest may be seen in women with cancer or pre-cancer treatment due to impaired emotional and physical health. These patients may tend to overlook their sexual well-being, adversely affecting their relationships with their partners [7]. Women experiencing sexual dissatisfaction exhibit lower psychological and general well-being. This underscores the significance of addressing sexual health and well-being in women as an integral component of their healthcare [8].

In the present study, parameters of sexual function like level of satisfaction, level of sexual desire or interest and vaginal self-lubrication showed significant improvement in cases post thermal ablation. This could

Table 6. Comparison of Sexual Parameters between the Two Treatment Groups before and after the Procedure

Sexual parameters	Pre-treatment			Post-treatment		
	Thermal ablation (n=27)	LEEP (n=24)	P value	Thermal ablation (n=27)	LEEP (n=24)	P value
Frequency [median (IQR)]	3 (2-3)	2 (1-3)	0.057*	3 (2-3)	1.5 (1-2)	<.0001[§]
Pain/discomfort during penetration n (%)	6 (22.22%)	6 (25%)	1*	4 (14.81%)	4 (16.67%)	0.815[†]
Post coital bleeding n (%)	2 (7.41%)	2 (8.33%)	1*	0%	0%	NA
Level of satisfaction[$]	3.3±0.47	3.08±0.41	0.096	3.07±0.27	2.25±0.61	<.0001[§]
Level of sexual desire or interest[$]	2.63±0.49	2.42±0.5	0.132[§]	3±0.39	2.17±0.7	<.0001
Vaginal self-lubrication[$]	2.56±0.51	2.42±0.65	0.219	3±0.39	2±1.02	<.0001
Flexibility of vagina[$]	2.7±0.47	2.58±0.5	0.374[§]	2.93±0.62	2.17±0.7	0.0004[§]
Ability to reach climax[$]	2.7±0.47	2.58±0.5	0.374[§]	2.63±0.74	2±0.72	0.008[§]
Level of anxiety related to sexual life[$]	2.33±0.48	2.44±0.51	0.422[§]	2.08±0.78	2.56±0.64	0.044
Overall level of sexual satisfaction[$]	2.7±0.47	2.83±0.38	0.281[§]	2.93±0.47	2.17±0.38	<.0001

[$], mean±SD; [§], Mann Whitney test; *, Fisher's exact test; [†], Chi square test

be attributed to post procedure decrease in dyspareunia and post-coital bleeding. Although, small but there was a statistically significant decrease in the level of satisfaction, ability to reach climax and level of patient perceived partner satisfaction post LEEP. Furthermore, there was a tendency toward a statistically significant change in vaginal lubrication and flexibility following LEEP. This was consistent with the results by Inna et al. (2010) who reported no difference in frequency of sexual intercourse, dysmenorrhea, dyspareunia, and postcoital bleeding post LEEP. They reported reduction in overall satisfaction, vaginal elasticity, and orgasmic satisfaction. They also found a marginal decrease in the vaginal lubrication although not significant [9].

However, four studies evaluating sexual and mental well being after treatment for cervical dysplasia found no difference post procedure [5,10–12]. Kim et al. (2023) reported no difference in the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale (FSDS) scores due to LEEP. There was no significant decrease in the frequency of sexual dysfunction, desire, arousal, lubrication, orgasm, satisfaction, and pain. Furthermore, there was no significant increase in the proportion of women experiencing sexual distress [12]. Serati M et al. [5] demonstrated that overall sexual function remained unchanged after LEEP; the only notable change was a significant worsening in sexual desire [5].

These studies imply that the minor cervical trauma after such minor surgical procedure may not be regarded as a factor causing organic sexual dysfunction. The negative impact on sexual function in these women are likely influenced by various psychological factors, particularly anxiety. Distinguishing these aspects of sexual function as purely physiological or psychological is challenging, as they are influenced by a combination of both factors. However, when it comes to vaginal elasticity and lubrication, the unfavorable change cannot be solely explained by the physiological impact of LEEP, which specifically targets cervical tissue and not vaginal tissue. Insufficient information about the causes and consequences of cervical smear abnormalities and dysplasia, and their treatment might be a key factor triggering anxiety [13]. We advocate for education and support even after the completion of treatments and during follow-up visits.

In the present study, thermal ablation showed significantly better sexual function compared to the LEEP. Level of satisfaction, sexual desire, lubrication, flexibility, ability to reach climax was significantly better after thermal ablation when compared to LEEP. This may be attributed to the nature of the procedure. Thermal ablation causes thermocoagulation of the underlying tissue which later sloughs off while LEEP involves removal of a section of cervix which may affect the distal nerve innervations and local vaginal microbiome.

To our knowledge this is the first randomized trial to compare sexual function post thermal ablation and LEEP. The inclusion criteria were robust and only histologically proven CIN2+ cases were included. A structured questionnaire tailored to our patient population was used and there was no lost to follow up. However, due to the limited number of participants, the efficacy estimates should be interpreted cautiously. Secondly, evaluating treatment success at 6 months was probably too early, even though we did not expect any discrepancies to emerge between the study groups, which were well balanced due to randomization. The study was conducted in a low resource setting, hence HPV test for screening could not be used which is the current standard of care.

In conclusion, thermal ablation and LEEP both treatment modalities are well accepted for cervical dysplasia with similar efficacy at 6 months. Thermal ablation showed advantages in procedure time and post-procedural pain but demonstrated variable effects on sexual function, improving satisfaction and desire. LEEP, on the other hand, showed a decrease in satisfaction and potential alterations in lubrication and flexibility. Further research with larger sample sizes and longer follow-up duration is recommended.

Author Contribution Statement

Anupama Bahadur, Rajlaxmi Mundhra and Mahima Mahamood MM planned the study design. Shalinee Rao was helped with histopathology and cytology. Mahima Mahamood MM collected clinical and follow up data. Ayush Heda and Sakshi Heda wrote the initial draft of the manuscript with input of all authors. AB and RM helped in critical review of all clinical details as well as numerical calculations. Yogesh Bahurupi helped in data analysis. All authors were actively involved at all stages of the study.

Acknowledgements

Approval

The study was approved by the institutional ethical committee of All India Institute of Medical Sciences, Rishikesh (IEC number: AIIMS/IEC/20/653) as student thesis

Data Availability

Data generated by the authors available on request

Study Registration: Clinical Trials Registry of India (CTRI Reg No: CTRI/2021/03/032424)

Conflict of Interest

None.

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